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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services, Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

November 13, 2000

To whom it may concern:

As a board-certified gastroenterologist I have been actively treating patients with a variety of gastrointestinal ailments for over 9 years and have found those with irritable bowel syndrome (IBS) to pose the greatest challenge. Our therapeutic options have been quite limited in the past but our evolving scientific understanding of neuroenteric pathways over the last decade has created the greatest hope for improvements in pharmacologic management of this condition.

The development of and marketing of alosetron (Lotronex®) has been a major step in the right direction. Since its commercial availability in March of 2000 I have prescribed the drug on numerous occasions and have found it to be an extremely useful medication in treating women with diarrhea-predominant IBS. I have seen first-hand how it has markedly improved the quality of life for many of my patients and have seen no significant side effects in my patients.

I have not seen any patient develop ischemic colitis or any life threatening complication. The major adverse effect that I have seen is constipation and with careful preparatory counseling, my patients have generally experienced no significant problems.

I am a member of our Institutional Review Board and since our center does perform clinical trials involving alosetron, I have had the privilege of seeing the details of the adverse events reported by other centers on this drug. I am not impressed that any of the case reports regarding ischemic colitis or the more recent reports of deaths related to alosetron use, clearly implicate this drug as a causative factor.

Having carefully scrutinized these cases and my own practice, I continue to have no hesitancy in prescribing this drug to carefully selected, appropriate patients who I feel may benefit from it. Like all drugs, patients need to monitored carefully and given information about potential adverse reactions. I feel that any thoughts of withdrawing or restricting this drug from the commercial U.S. market would not be warranted based on

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the available information and would have a major negative impact on the lives of our patients who depend on it to maintain their quality of lives.

Sincerely yours,

Philip E. Jaffe, MD, FACP, FACG
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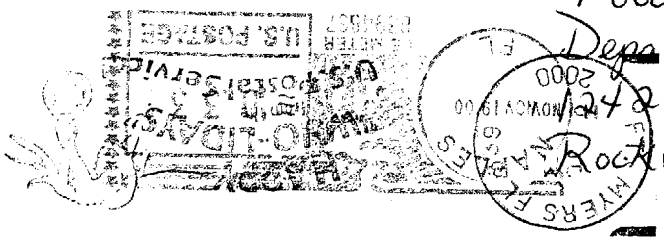

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